Remarks/Arguments

In the Specification: New paragraph [0030.1] is added in response to the rejection regarding the deposit of biological materials (Office action pages 2 – 4). The amendment should remove any doubt about enablement regarding the deposit. No new matter has been added. As stated in MPEP 2406.01, addition of information on the depository and deposit date does not violate the prohibition against new matter. This additional information was discussed with Examiner Mark Navarro, in the telephone interview of 15 June, 2005. For the phone interview, the contract with the depository was provided as an exhibit. An Appendix with the exhibit is attached to this paper.

In the Claims: Possible claim amendments were discussed with Examiner Mark Navarro, in the telephone interview of 15 June, 2005, along with questions concerning the prima facie case of nonenablement (see Errors in Rejection below). No agreement was reached regarding the claims. Claim 1 has been amended to correct a minor editorial problem (a missing period) that was pointed out in the Office action. New Claims 2 – 10 are added, and are supported by the original Specification.

Errors in Rejection

The assignee respectfully asserts that it was erroneous to reject Claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. A prima facie case of nonenablement has not been

established.

Argument regarding 35 U.S.C. 112, first paragraph, and lack of a prima facie case of nonenablement:

A) As stated in MPEP 2164.04, "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. [Citing *In re Wright*] ... (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure)." The Office action has failed to provide a reasonable explanation directed to the scope of rejected Claim 1 in this case: a "vaccine strain."

B) As stated in MPEP 2164, "to comply with 35 U.S.C. 112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.'" [Citing *CFMT, Inc.*] The Office action's insistence on prevention is an improper insistence on enabling a perfected, commercially viable embodiment. It is improper because Claim 1 does not describe a perfected, commercially viable embodiment. Claim 1 should be read in light of the following material in the Specification for example: "a vaccine strain of Bacillus anthracis *from which may be produced* an improved anthrax vaccine ... a vaccine strain of Bacillus anthracis that will *enable identification of new genes* that contribute to the pathogenesis of the organism and thereby elucidate new antigens that play a role in eliciting a specific, protective

immune response early in the infection process." Specification Paragraph [0021][emphasis added]. "A genetic fingerprint comparison of the mutant Alls/Gifford with the paternal Sterne strain should reveal the altered genes of the mutant. The protein products of the altered genes found by comparison to Sterne *could form the basis for a vaccine* that would stimulate antibody to inhibit the bicarbonate/CO2/heat- stimulated growth of anthrax that is necessary for its development in the host." Specification Paragraph [0032] [emphasis added].

C) As stated in MPEP 2164.04, "References should be supplied if possible to support a prima facie case of lack of enablement ..." In this case, the Office action has not supplied a reference that supports a prima facie case of lack of enablement. The published application of Simonson, 20030143636A1, cited by the Office action, is not relevant to the language of rejected Claim 1. The Simonson reference does not contain the phrase "vaccine strain" that is used in Claim 1. In contrast, Simonson contains a discussion of "challenge strains" used to challenge lab animals (for example, see Simonson paragraphs 37, 40, 45, and 50). Simonson comments on "variability of survival outcomes in animal models" and "the differing virulence of the challenge strains ...." Simonson paragraph 50.

D) Regarding the deposit of biological materials, Claim 1 is rejected based on minor omissions that are mere informalities, at worst. The Office action has not established a reasonable basis to question enablement, nor a

reasonable basis to question the deposit. MPEP 2411.01 provides for a rejection only if "there is *no information* that would support the conclusion that access is currently available in accordance with these regulations [emphasis added]." In this case, the original Specification contains definite information: "Bacillus anthracis Alls/Gifford strain is currently on deposit at the American Type Culture Collection under the designation PTA-3162." Specification Paragraph [0030].

In conclusion, the Office action has not established a reasonable basis to question enablement. A prima facie case of nonenablement has not been established. Assignee respectfully submits that the rejection of Claim 1 should be withdrawn, and requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Attachment